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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,406	01/22/2001	Michael S. Halpern	7933-38	5749

7590 06/03/2005

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/744,406	Applicant(s) HALPERN ET AL.	
	Examiner Christopher H. Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Halpern *et al*

1. The amendment filed 3/21/2005 is acknowledged and entered into the record. Accordingly, claims 1-39 are canceled without prejudice or disclaimer.
2. Claims 40-43 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

4. The rejection of claims 40-43 under 35 USC § 112, 1st paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the instantly claimed invention is drawn to a cellular immunogen that has been transfected with a vector comprising a non-transforming transgene cognate to a target proto-oncogene and that the arguments concerning the unpredictability of in vivo gene therapy are irrelevant. Specifically, applicant argues that the techniques of ex vivo gene transfer are well known and recognized in the art. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Contrary to applicant's arguments, the claims as currently interpreted do in fact read on gene therapy. As indicated in the office action mailed 10/20/2004, the use of a cellular immunogen that has been transfected with a vector comprising a non-transforming transgene cognate to a target proto-oncogene for the purposes of gene therapy are in fact unpredictable. The specification has not provided a nexus between

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the working examples provided in the specification and a means of generating an immune response against said proto-oncogenes claimed.

Therefore, given the unpredictable nature of the claimed invention and the lack of sufficient disclosure regarding the use of the claimed invention for the purposes of gene therapy, the rejection of the claims under 35 USC 112, 1st paragraph is maintained.

Claim Rejections Maintained - 35 USC § 102

5. The rejection of claims 40-43 under 35 USC § 102(e) as being anticipated by Chada *et al* (US Patent 5,693,522) is maintained for the reasons of record. Applicant argues that Chada *et al* teach mutations outside of the deletion site. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). In the instant case, the product claimed appears to be identical to that taught by Chada *et al*. Applicant distinguishes the prior art product from that of the instant invention by claiming means of making the claimed product. Because the instant claims do not specifically limit the sequences that are critical or essential for the transformation, the

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deletions as taught by Chada *et al* are deemed to read on the "sequences of the transgene essential for the transformation" as claimed. Moreover, because the office does not have the facilities to determine if the sequences taught by Chada *et al* are in fact essential for transformation as claimed, it is incumbent upon the applicant to provide factual evidence to indicate otherwise.

Therefore the rejection of claims under 35 USC 102(e) as being anticipated is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 102

6. The rejection of claims 40 and 42 under 35 USC § 102(b) as being anticipated by Gelman *et al* (Oncogene 1993; 8(11):2995-3004) is maintained for the reasons of record. Applicant argues that the cited reference does not teach each and every limitation of the claimed invention. Specifically, applicant argues that Gelman *et al* does not teach deletions in the sequence necessary for transformation. Applicant further contends that the cell lines disclosed by Gelman *et al* are in fact transforming. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re

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Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). In the instant case, as indicated above (see paragraph 5), the applicant has claimed a product that appears to be the same as that taught in the prior art. Specifically, the cellular immunogen taught by Gelman *et al* is non-transforming, because Gelman *et al* teach cell lines that are not capable of forming tumors, hence non-transforming (see in particular table 1- cell line B (1720/*c-src*)). Moreover, because the specification nor the claims specifically indicate which portions of the sequence are deemed essential for transformation, and because the office does not have the facilities to determine that the modifications made to the gene found within cell line B 1720/*c-src* are in fact different, in the absence of evidence to the contrary, they are the same because both the claimed product and that taught in the prior art are non-transforming.

Therefore, the rejection under 35 USC 102(b) as being anticipated is maintained for the reasons of record.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 3/21/2005.

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Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

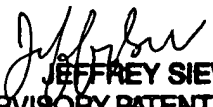
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
May 17, 2005


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
5/31/05